

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE APPLICATION OF:

ANTHONY J. KINNEY ET AL.

CASE NO.: BB1538USNA

APPLICATION NO.: 10/776311

CONFIRMATION NO.: 4023

GROUP ART UNIT: 1638

EXAMINER: DAVID T. FOX

FILED: FEBRUARY 11, 2004

FOR: PRODUCTION OF VERY LONG CHAIN POLYUNSATURATED FATTY ACIDS
IN OIL SEED PLANTS

Via EFS-Web

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Reply Brief Submitted Pursuant to 37 CFR §41.41

This is a Reply Brief submitted in response to the Examiner's Answer dated June 23, 2009 which was filed in response to the appeal brief filed February 10, 2009 and supplemented on March 20, 2009 appealing from the Office Action mailed July 16, 2008.

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(I) Real Party in Interest

The real party in interest in this Appeal is E. I. du Pont de Nemours and Company, the assignee of the entire right, title and interest of the above-identified patent application.

(II) Related Appeals and Interferences

There are no related Appeals or Interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

(III) Status of Claims

Claims 1-139 were originally filed.

A Restriction Requirement was issued and the subject matter of Group I, Claims 1, 11, 12, 16-18 and 26-28 were elected for further prosecution. Claims 11, 17, 18, 27 and 28 were cancelled during prosecution. There is one independent claim: 1.

The currently pending and appealed claims are claims 1, 12, 16 and 26 which are set forth in the Claims Appendix attached hereto.

(IV) Status of Amendments Filed Subsequent to Final Rejection

A first Response after Final was filed electronically on March 14, 2008. Finality of the Office Action mailed on February 6, 2008 was withdrawn and prosecution was reopened. A second Response After Final was filed electronically on October 10, 2008. This second Response After Final was not entered as set forth in the Advisory Action re-issued and dated January 21, 2009

(V) Summary of the Invention

The invention on appeal is believed to constitute pioneering work wherein an exogenous DHA and/or EPA biosynthetic pathway was incorporated into an oilseed plant thereby enabling the oilseed plant to produce, for the first time, at

least 1% DHA and/or EPA in the seed oil. This simply was not known prior to Applicants' disclosure.

Claim 1 concerns a transgenic oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 1.0% of at least one omega -3 polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds wherein said transgenic oilseed plant comprises in its genome at least two transgenic nucleic acid sequences encoding at least two different polypeptides and further wherein at least one polypeptide has desaturase activity and at least one polypeptide has elongase activity.

This is discussed in the specification, *inter alia*, on page 17 starting at line 3 through line 2 on page 19, Examples 3-8 and 10-13, and claims 1, 11 and 12 as originally filed.

Claim 12 concerns the oilseed plant of claim 1 wherein the polyunsaturated fatty acid is an omega-3 fatty acid selected from the group consisting of eicosapentaenoic acid (EPA), docosapentaenoic acid (DPA), and docosahexaenoic acid (DHA).

This is discussed in the specification, *inter alia*, on page 4 at lines 17-18, on page 17 starting at line 37 through line 2 on page 18, and Examples 11 and 13 and in claim 12 as originally filed.

Claim 16 concerns seeds obtained from the transgenic plant of claim 1 or 12 wherein the seed comprises the transgenes.

This is discussed in the specification, *inter alia*, on page 4 at lines 3-8, pages 24 and 25, and Examples 4 and 5.

Claim 26 relates to the transgenic oilseed plant of claim 1 or 12 being selected from the group consisting of soybean, Brassica species, sunflower, maize, cotton, flax, and safflower.

This is discussed in the specification on page 17 at lines 35-36 and in claim 26 as originally filed.

(VI) Grounds of Rejection To Be Reviewed on Appeal

One ground of rejection remains for review:

Whether claims 1,12, 16 and 26 are obvious under 35 USC §103(a) over Knutzon et al. (U.S. Patent No. 6, 075, 183 issued June 2000) in view of Abbott Laboratories (WO 02/08401), further in view of each of Mukherji et al. (U.S. 7, 211,656) or Browse et al. (U.S. Patent no. 6,884,921).

(VII) Argument

The rejection of claims 1,12, 16 and 26 as obvious under 35 USC §103(a) over Knutzon et al. (U.S. Patent No. 6, 075, 183 issued June 2000) in view of Abbott Laboratories (WO 02/08401), further in view of each of Mukherji et al. (U.S. 7, 211,656) or Browse et al. (U.S. Patent no. 6,884,921).

As was stated previously, it should be noted that the instant application was filed non-provisionally on February 11, 2004 and claims the benefit of priority of a provisional application that was filed on **February 12, 2003**. Thus, Appellants appear to have filed one of the earliest provisional patent applications pertaining to engineering oilseed crops to produce at least about 1% **omega-3** fatty acids having at least **twenty** carbon atoms and **five** or more carbon-carbon double bonds. A corresponding non-provisional patent application was filed on February 11, 2004 along with a PCT International Application that was published on August 26, 2004.

Reliance upon Abbadi et al. (October 2004) and Qi et al. (June 2004) is misplaced as these articles were published after the February 12, 2003 priority date to which the instant Application is entitled.

As was stated on page 5 of the Appeal Brief, it was not known prior to Appellants' disclosure that an exogenous DHA and/or EPA biosynthetic pathway could be placed into an oilseed plant and from which at least about 1.0% of DHA and/or EPA could be recovered. Both DHA and EPA are omega-3 fatty acids having at least twenty carbon atoms and five or more carbon-carbon double bonds.

It was stated in the first paragraph on page 5 of the Examiner's Reply Brief that "Knutzon et al teach that said transgenic Brassica plants produces seeds with oil comprising over 11% of new fatty acids including the DGLA precursor."

The composition of T2 pooled seed is presented in Table 4 and a Fatty Acid Analysis of Seeds from Ma524 Transgenic Brassica Plants is presented in Table 5.

There is no data presented, in either of the Knutzon tables, for fatty acids having at least twenty carbons and five or more carbon-carbon double bonds. Kunutzon does present data for fatty acids having at least twenty carbon atoms and at least one carbon-carbon double bond; however, this data does not appear to add up to about 11%.

Furthermore, DGLA is an **omega-6** fatty acid.

The data presented in Knutzon Table 4 shows that all of the 5538 lines except #8 produced seeds containing GLA. (Knutzon '183 column 24 at lines 14-19). GLA is an omega-6 fatty acid which is not part of the claimed invention.

It was mentioned in Knutzon, column 24 at lines 16-19, that the *M. alpina* delta-6 desaturase is capable of producing 18:4 (stearidonic) and another fatty acid believed to be the 6,9-18:2. Stearidonic acid is an omega-3 fatty acid having only 18 carbons and four carbon-carbon double bonds. Again, this is not part of the claimed invention.

What was stated in Knutzon, column 24 at lines 23-26, is that **what was exemplified** "were the production of ARA (20:4) from the precursor 20:3 (DGLA), the production of GLA (18:3) from 18:2 substrate, and the conversion of 18:1 substrate to 18:2, which is the precursor of GLA."

ARA, DGLA and GLA are all omega-6 fatty acids.

It is stated in column 3 at lines 21-28 that FIG. 1 show possible pathways for the synthesis of arachidonic acid and stearidonic acid from palmitic acid from a variety of organisms, including algae, Mortierella and humans.

Although Figure 2 of Knutzon sets forth possible pathways for producing both omega-3 and omega-6 fatty acids compiled from a variety of organisms, Knutzon et al. **never** transformed an oilseed crop to produce any (let alone at

least about 1%) omega-3 fatty acids having at least twenty carbon atoms and five or more carbon-carbon double bonds wherein the transgenic oilseed plant comprises in its genome at least two transgenic nucleic acid sequences encoding at least two different polypeptides and further wherein at least one polypeptide has desaturase activity and at least one polypeptide has elongase activity.

The discussion on page 13, first full paragraph, of the Examiner's Reply Refers to the production of fatty acids that are all outside the scope of the claimed invention.

It is worth reiterating that claim 1 of the instant invention recites a transgenic oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 1.0% of at least one omega -3 polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds wherein said transgenic oilseed plant comprises in its genome at least two transgenic nucleic acid sequences encoding at least two different polypeptides and further wherein at least one polypeptide has desaturase activity and at least one polypeptide has elongase activity.

The Abbott Laboratories reference is equally in apposite for all of the reasons discussed herein.

It was stated on page 6 of the Examiner's Reply that "Mukerji et al. teach that omega-3 desaturase and delta-17 desaturase are synonymous, and that this enzyme is required for the production of EPA, which has nutritional and pharmaceutical applications. . . ."

Browse et al. state in column 3 at lines 21-25 that they "have cloned fat-1, and omega-3 fatty acyl desaturase gene from *Caenorhabditis elegans*. When expressed in a wide range of host cells, the polypeptide encoded by fat-1 catalyzes the **introduction of an ω -3 double bond into 18-, 20-, and 22-carbon fatty acids**. . . ." (Emphasis added.) It appears that the only expression work done by Browse et al. was in yeast.

Mukerji et al. state in column 35 at lines 23-30 that the "sdd17 encodes a novel omega-3 desaturase, capable of desaturating C20 and C22 fatty acid substrates. . . . This enzyme is very different from other known omega-3

desaturases, **showing activity on both C20 and C22 fatty acid substrates, but not 18 substrates.** . . . “ (Emphasis added.)

Thus, the Browse omega-3 desaturase acted on 18-, 20- and 22- carbon fatty acids while the Mukerji omega-3 desaturase acted on 20- and 22- carbon fatty acid but NOT on 18- carbon fatty acids. Furthermore, Mukerji et al. only obtained about **0.14% EPA in yeast** (less than 1%) as set forth in Table 6 (column 36 of Mukerji et al.).

Given that none of these references showed any work in plants and only one (Mukerji et al.) produced about 0.14% EPA in yeast (Table 6 , column 36, Mukerji et al.) , it would not have been obvious to one of ordinary skill in the art to reasonably expect to combine the teachings of the references in order to make a transgenic oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 1.0% of at least one omega -3 polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds wherein said transgenic oilseed plant comprises in its genome at least two transgenic nucleic acid sequences encoding at least two different polypeptides and further wherein at least one polypeptide has desaturase activity and at least one polypeptide has elongase activity.

(VIII) Conclusion

In view of the foregoing discussion, it is respectfully submitted that: claims 1,12, 16 and 26 are not obvious under 35 USC §103(a) over Knutzon et al. (U.S. Patent No. 6, 075, 183 issued June 2000) in view of Abbott Laboratories (WO 02/08401), further in view of each of Mukherji et al. (U.S. 7, 211,656) or Browse et al. (U.S. Patent no. 6,884,921).

Accordingly, the Board is respectfully requested to reverse the final rejection of pending claims 1, 12, 16 and 26 and indicate allowability of all claims.

Please charge any fees associated with the filing of this Reply Brief submitted in response to the Examiner's Answer dated June 23, 2009 to Appellant's Assignee's (E. I. du Pont de Nemours and Company) Deposit Account No. 04-1928.

Respectfully submitted,

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Claims Appendix

Claim 1. (previously presented) A transgenic oilseed plant that produces mature seeds in which the total seed fatty acid profile comprises at least 1.0% of at least one omega -3 polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds wherein said transgenic oilseed plant comprises in its genome at least two transgenic nucleic acid sequences encoding at least two different polypeptides and further wherein at least one polypeptide has desaturase activity and at least one polypeptide has elongase activity.

Claim 12. (previously presented) The oilseed plant of Claim 1 wherein the polyunsaturated fatty acid is an omega-3 fatty acid selected from the group consisting of eicosapentaenoic acid (EPA), docosapentaenoic acid (DPA), and docosahexaenoic acid (DHA).

Claim 16. (previously presented) Seeds obtained from the plant of Claim 1 or 12 wherein said seeds comprise the transgenes.

Claim 26. (previously presented) The plant of Claim 1 or 12 wherein the oilseed plant is selected from the group consisting of soybean, Brassica species, sunflower, maize, cotton, flax, and safflower.

Related Proceedings Appendix

None